DIAGNOSTICA PRODUCTS

Liquid Reagents – ready to use

RF 5+1

Diagnostic reagent for the quantitative in vitro determination of RF (Rheumatoid Factor) in human serum by turbidimetric assay.

Ref.No.	Kit Size	Content
DIA020040	60 ml	2x25 ml R1 + 1x10 ml R2
DIA020041	120 ml	4x25 ml R1 + 1x20 ml R2
DIA020042	6 x 25 ml	5x25 ml R1 + 1x25 ml R2

Additionally offered:

DIA040040	1 x 1 mL	RF Calibrator High
DIA030060	1 x 1 mL	RF Control High
DIA030090	1 x 1 mL	Triple Control (ASO, CRP, RF)

GENERAL INFORMATION

Method	Immunoturbidimetric
Reaction	Nonlinear, endpoint
Wavelength	340 nm
Assay Temperature	18 – 37 °C
Sample	Serum
Measuring Range	approx. 0 – 500 IU/mL
Sensitivity	3 IU/mL (Hitachi 911)
Hook Effect	No risk

REAGENT COMPOSITION

COMPONENTS	CONCENTRATION
RF Antibody Reagent	
Suspension of heat-aggregated human IgG in glycine buffer	variable
Sodium azide	0.095 %
RF Buffer	
Good's Buffer	50 mmol/L
Sodium azide	0.095 %

REAGENT PREPARATION

The reagents are liquid and ready to use.

REAGENT STABILITY AND STORAGE

Conditions: Protect from light. Close immediately after use.

Stability: at 2 – 8 °C up to the expiration date
at 18 – 25 °C 1 month

Do not freeze!

SAMPLE STABILITY AND STORAGE

Stability: at 2 – 8 °C 48 hours
at – 20 °C 3 months

Freeze only once!

TEST PRINCIPLE

The assay of RF is based on turbidimetric measurement. Turbidity is caused by the formation of antigen-antibody insoluble immuno complexes.

REFERENCE RANGE

0 – 20 IU/mL (WHO)

It is recommended that each laboratory establishes its own normal range.

MANUAL TEST PROCEDURE

Test Procedure without Sample Dilution:

Samples/Controls: ready to use
Calibration curve: Use RF Calibrator Super High to generate a calibration curve by making 1:2 serial dilutions of the calibrator with 0.9% saline as diluent or use the 5 level calibrator series. Use 0.9% saline as zero point.

Pipette into test tubes:	Calibrators	Samples/Controls
Buffer	900 µL	900 µL
Cal./Ctrls/Samples	50 µL	50 µL
Mix. Read A1 of calibrators and samples/controls at 340 nm. Then add:		
Antibody Reagent	180 µL	180 µL
Mix. Incubate 5 minutes at assay temperature. Read A2 of calibrators and samples/controls at 340 nm. Calculate: ΔA = (A2 – A1)		

CALCULATION

Calculate and plot ΔA = (A2 – A1) of the calibrators versus assigned concentration values on a linear-linear graph paper. Calculate ΔA optical densities of samples and control(s) and read values in IU/mL on the reference curve. Samples yielding absorbances above highest calibrator should be retested after further dilution.

DIAGNOSTIC IMPLICATIONS

The diagnosis of rheumatoid arthritis (RA) is based largely on clinical examination, but laboratory tests (e.g. RF Test) are useful to support the clinical diagnosis and to evaluate the severity and course of the disease in the individual patient. RF is a term used to describe a variety of antibodies (in most cases of the IgM type) that will react with modified human IgG (e.g. IgG in circulating immune complexes, IgG adsorbed to latex, etc.) and IgG of animal origin. RF is highly associated with rheumatoid arthritis, as high as 90 % of patients with RA have RF titers of more than 50 IU/mL.

PERFORMANCE CHARACTERISTICS

SENSITIVITY

3 IU/mL (Hitachi 911)

ACCURACY

Control	Assigned Value (IU/mL)	Measured Value (IU/mL)
INTERNAL	111 (94 – 128)	105
BIO-RAD 1	19.6 (16.6 – 22.5)	18.0
BIO-RAD 2	39.8 (33.8 – 46.2)	39.7

PRECISION

Intra-Assay Precision

3 Serum Samples were consecutively measured on a Hitachi 911.

Expected Values	n	C.V.
Low	20	2.68
Medium	20	1.38
High	20	1.55

Inter-Assay Precision

3 Serum Samples with low, medium and high value of RF were measured on a Hitachi 911 at regularly time intervals during one week. The sera were stored at 4°C after each use.

Sample	n	C.V.
Low	12	3.57
Medium	12	1.34
High	12	1.91

METHOD COMPARISON

A comparison with Nephelometry gave the following results:
y = 0.6026x + 32.5; r = 0.8776

INTERFERING SUBSTANCES

No interference up to:

Triglycerides	2500 mg/dL	Hemoglobin	500 mg/dL
Bilirubin	20 mg/dL	Sodium Citrate	1000 mg/dL
Heparin	50 mg/dL	Turbidity	5 mg/dL

QUALITY CONTROL

All commercially available control sera with RF values measured by this method may be used.

CALIBRATION

The assay requires the use of RF serum calibrators.

DIAGNOSTICA PRODUCTS, RTE DE GABES KM 9 Z.I THYNA AL JADIDA SFAX, TUNISIA.
Tel. +216 74 68 79 40 Fax. +216 74 68 79 32

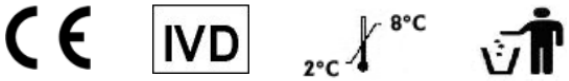
REV. 01, 22.11.2017

WARNINGS AND PRECAUTIONS

1. The RF reagents are intended for in vitro diagnostic use only.
2. Sodium azide has been reported to form lead or copper azide in laboratory plumbing which may explode on percussion.
3. Each donor unit used in the preparation of the standards and controls was found to be negative for the presence of HIV antibodies, as well as for Hepatitis B surface antigen, using a method approved by the FDA
4. Avoid eyes and skin contact. If contact, flush with a large amount of water. If irritation persists, consult a physician

WASTE MANAGEMENT

Please refer to local requirements.



DIAGNOSTICA PRODUCTS, **RTE DE GABES KM 9 Z.I THYNA AL JADIDA SFAX, TUNISIA.**
Tel. +216 74 68 79 40 Fax. +216 74 68 79 32